Minister's talking points for Launch of the SA National Action Plan on combatting Substandard and Falsified medical products – Protea Hotel OR Tambo

Tuesday, 30 September 2025

- Thank you Mr Facilitator, Prof JJ Tabane
- World Health Organization Country Director, Ms Shenaaz El-Halabi
- SAHPRA CEO, Dr Boitumelo Semete-Makokotlela
- Representatives from Medicines Agency
- Representatives from AUDA-NEPAD- African Medicine Regulators Harmonisation (AMRH),
- Representatives from SADC SF committee
- Representatives from AUDA-NEPAD
- Representatives from Bill Gates and Melinda Gates
- Representatives from Fleming fund
- The Multisectoral Committee that developed the South African National Action Plan on combatting SFs

It is my pleasure to be part of this important gathering, though I could not be physically with you in the room because of other commitments of national importance. We have extended cabinet meeting with President, Ministers, Deputy Ministers and Premiers.

South Africa in collaboration with the World Health Organization (WHO) led by SAHPRA are conducting a pilot on the National Action Plan (NAP) on fighting Substandard and Falsified (SFs) Medical Products, a member state mechanism which its success

will inform rolling out the National Action Plan handbook to the UN Member states.

This has been a year long journey and I am delighted to officially launch this developed National Action Plan today. The purpose of this launch is to officially present the developed five-year National Action Plan on combatting substandard and falsified medical products, and to mark the end of the RSA WHO pilot on the draft Handbook on combatting Substandard and Falsified medical products.

Through this bold initiative, South Africa is positioned among the first countries globally to operationalise a comprehensive strategy against Substandard and Falsified medical products. The National Action Plan aims to strengthen prevention, detection and response mechanisms through a coordinated multi-sectoral action as guided by the National Action Plan draft Handbook developed for this purpose by the WHO. This milestone demonstrates South Africa's leadership and commitment to safeguarding access to quality, safe, and effective medical products.

The event also serves as a platform to mobilise political, technical, and financial support for implementation, while raising public and media awareness about the dangers posed by substandard and falsified medical products. The WHO handbook mention importance of political commitment, resources and sustained, coordinated action to combat SF medical products and restore or maintain trust in health systems. This will affirm South Africa's leadership and political commitment to this critical public health issue

The World Health Organisation defined Falsified medical products as medical products that deliberately or fraudulently misrepresent their identity, composition, or source, and these have not even been authorised by the regulator to be in the

market. Substandard Medical products are authorized medical products that fail to meet their quality standards or specifications, or both. This can occur due to poor manufacturing practices, inadequate quality control, or other unintentional errors during production. These products may not work as intended and can pose significant risks to patient health.

Substandard and falsified medical products are a threat individual lives and integrity of health systems globally. As we launch the National Action Plan against falsified and substandard medical products, we reaffirm our commitment as the Department to ensuring that every medicine, every vaccine, and every health product available to our people is safe, effective, and is of the highest degree of quality.

A significant percentage of Substandard and Falsified products circulating globally are found in Africa and this presents a serious concern for public health, affecting the attainment of Sustainable Development Goals (SDG) 3, which aims to ensure universal health access for all. A common finding from the WHO Global Benchmarking Tool assessments in various countries is the need to strengthen the market surveillance and control function – which fights the SFMPs.

The WHO draft Handbook frames the strategic objectives and goals, with actions, inputs, outputs and outcomes used for developing strategic and operational plans, and provides insights into approaches for operational planning, monitoring and evaluation.

The developed National Action Plan (NAP) provides a framework for addressing the threat of SF medical products and supports strengthened technical capacity and stakeholder collaboration across all parties engaged in the manufacture, importation, distribution, and supply of medical products.

All actors within the supply chain, particularly at key pinch points in both the public and private sectors, must be equipped with the knowledge, skills, and equipment to identify and report suspicious products to SAHPRA. All activities should mitigate the risk of SF medical products. This includes increased vigilance at ports of entry, through to post market surveillance of high-risk products, inspection of manufacturers, distributors and wholesalers.

The Fifth Ordinary Session of the African Union Specialised Technical Committee on Health, Population, Nutrition And Drug Control held in Addis Ababa, Ethiopia on 5-9 August 2024 (Expert Session &Ministerial session) expressed the deeply concern regarding the proliferation of substandard and falsified medical products (SFMP) on the continent which poses a real threat to public health and economy loss in Africa.

The number of substandard and falsified medical products incidents from Africa reported through the WHO Global Surveillance Monitoring System have been increasing over the years. In October 2022, several deaths of children registered in the Gambia were linked to substandard medical products.

WHO in 2012, established the Member State Mechanism on Substandard and Falsified Medical Products the global forum at which Member States convene, coordinate, decide and organize activities to address substandard and falsified medical products. South Africa chairs the Governance working group of the MSM also known as "*Leveraging the competencies of relevant stakeholders, including policymakers, procurers, distributors, practitioners, patients and consumers, and good governance to reduce the burden of substandard and falsified medical products*".

I therefore commend the joint effort of South Africa led by Health via SAHPRA and WHO for conducting a pilot study to implement the WHO draft Handbook on developing the National Action Plan for combatting Substandard and Falsified medical products.

The National Action Plan was developed through a multi-sectoral process involving government, regulators, enforcement agencies, academia, industry patient and advocacy representatives. The process was informed by the pilot implementation of the WHO Draft Handbook for the National Action Plan on Substandard and Falsified Medical Products.

The pilot tested practical arrangements to prevent, detect, and respond to SF products across the supply chain, while generating lessons to guide national scale-up. Insights from the pilot informed the refinement of the National Action Plan, ensuring that it is context-specific and operationally feasible.

A multisectoral Steering Committee was established, with SAHPRA as Secretariat, and Technical Working Groups drawn from government departments, regulators, enforcement agencies, academia, and industry. This inclusive and evidence-based process ensured that the National Action Plan reflects national priorities, aligns with WHO guidance, and provides a coordinated framework for implementation.

The launch represents a milestone in protecting the integrity of South Africa's health system and medicines supply chain. The network that strives to protect public health by sharing knowledge, resources, and best practices for the betterment of our health system.

The launch aims to present the National Action Plan framework and its three key pillars of prevention, detection, and response strategy. It will :

- Secure commitment from the Ministry of Health and partner departments, while also highlighting the critical roles of the Steering Committee and Technical Working Groups in driving implementation.
- Furthermore, strengthen collaboration among all internal and external stakeholders.
- Actively engage the media as a channel to promote greater public awareness of the Substandard and Falsified medical products and understanding of the National Action Plan.

The expected outcomes of the launch include the formal endorsement of the National Action Plan by the Minister of Health, reinforced commitments from national stakeholders and other partners, and the elevation of South Africa's profile as a leader in the fight against substandard and falsified medical products.

The event will also secure broad media coverage to raise awareness and strengthen public confidence in the integrity of the medicines supply chain and the health system.

The National Action Plan against SFPMs strengthens the SAHPRA led market surveillance and control activities. It is therefore my hope that in November 2025, the WHO Global Benchmarking Tool (GBT) reassessment of South Africa, we will retain our Maturity Level 3 status.

In conclusion, I thank the WHO for choosing South Africa for this opportunity and we are ready to preset this pilot journey with the Member State Mechanism on SFs at its 14th meeting to be held in November 2025, Geneva Switzerland. I trust that this will encourage member states to develop their own National Action Plan using the draft Handbook.

We are proud of SAHPRA for leading this governance structure and we thank the government department, non-government organisations, health sector industry and business for their commitment to this initiative. I therefore urge the National Action Plan committee to continue stronger from here as this marks the beginning of the actual National Action Plan journey of Implementation, continuous monitoring and evaluation of the developed five-year NAP.

Regulators on the African continent and globally will be watching and scrutinising our implementation journey, therefore we should keep encouraging them to continue collaboration and strategizing on medium to long-term priorities and interventions regarding the prevention, detection and response to substandard and falsified medical products on the continent.

I wish you robust and fruitful discussion

I Thank You